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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,203	03/13/2002	Tracey Brown	HACK:011US	8511

7590 09/10/2004

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600 Congress Avenue Suite 2400  
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EXAMINER
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FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 09/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/889,203	<b>Applicant(s)</b> BROWN, TRACEY	
	<b>Examiner</b> Blessing M. Fubara	<b>Art Unit</b> 1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 April 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Examiner acknowledges receipt of request for extension of time, amendment and remarks filed 04/19/04. Claims 1-9 are pending.

#### ***Claim Rejections - 35 USC § 112***

1. The rejection of claim 8 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn because amended claim 8 recites "drug."

#### ***Claim Rejections - 35 USC § 102***

2. Claims 1-7 and 9 remain rejected under 35 U.S.C. 102(b) as being anticipated by Falk et al. (WO 91/04058).

Applicant argues that the molecular weight of hyaluronic acid in Falk is less than 750,000 Daltons and the claims as amended requires hyaluronate having a molecular weight of greater than or equal to about 750,000 Daltons.

3. Applicant's arguments filed 04/19/04 have been fully considered but they are not persuasive.

A molecular weight of less than 750,000 Daltons reads a molecular weight of equal to about 750,000 Daltons.

4. Claims 1-7 and 9 remain rejected under 35 U.S.C. 102(e) as being anticipated by Falk et al. (US 5,985,850).

Applicant argues that the molecular weight of hyaluronic acid in Falk is less than 750,000 Daltons and the claims as amended requires hyaluronate having a molecular weight of

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greater than or equal to about 750,000 Daltons and that use of hyaluronate of molecular weight of greater than or equal to about 750,000 Daltons distinguishes over Falk.

5. Applicant's arguments filed 04/19/04 have been fully considered but they are not persuasive.

A molecular weight of less than 750,000 Daltons reads a molecular weight of equal to about 750,000 Daltons and thus the claims are not distinguished over Falk.

6. Claims 1, 6,7 and 9 remain rejected under 35 U.S.C. 102(e) as being anticipated by Turley et al. (US 6,475,795).

Applicant argues that Turley does not disclose the use of hyaluronans having molecular weight of greater than or equal to about 750,000 Daltons, Turley does not therefore teach every element of the claims and the claims are not anticipated by Turley.

7. Applicant's arguments filed 04/19/04 have been fully considered but they are not persuasive.

Applicant admits that Turley discloses the use of hyaluronan having molecular weight of less than 750,000 Daltons and less than 750,000 Daltons reads on a molecular weight of equal to about 750,000 Daltons and thus Turley discloses that element of the instant claims and thus meets the limitations of the designated claims.

8. Claims 1-7 and 9 remain rejected under 35 U.S.C. 102(1) as being anticipated by Falk et al. (US 5,985,580).

Applicant traverses this rejection on the basis that Falk does not teach hyaluronan having a molecular weight of greater than or equal to 750,000 Daltons as required by the amended claims.

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9. Applicant's arguments filed 04/19/04 have been fully considered but they are not persuasive.

Applicant admits that Falk discloses the use of hyaluronan having molecular weight of less than 750,000 Daltons and less than 750,000 Daltons reads on a molecular weight of equal to about 750,000 Daltons and thus Falk discloses that element of the instant claims and thus meets the limitations of the designated claims.

10. Claims 1, 6, 7 and 9 remain rejected under 35 U.S.C. 102(a) as being anticipated by Turley et al. (US 6,475,795).

Applicant argues that Turley does not disclose the use of hyaluronans having molecular weight of greater than or equal to about 750,000 Daltons, Turley does not therefore teach every element of the claims and the claims are not anticipated by Turley.

11. Applicant's arguments filed 04/19/04 have been fully considered but they are not persuasive.

Applicant admits that Turley discloses the use of hyaluronan having molecular weight of less than 750,000 Daltons and less than 750,000 Daltons reads on a molecular weight of equal to about 750,000 Daltons and thus Turley discloses that element of the instant claims and thus meets the limitations of the designated claims.

***Claim Rejections - 35 USC § 103***

12. Claim 8 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Falk et al. (US 5,985,850).

Applicant argues that because Falk does not disclose use of hyaluronan having a molecular weight of greater than or equal to about 750,000 Daltons, the claimed invention cannot

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be obvious over Falk. Applicant then cites Turley, column 10, lines 13 and 14 as disclosing that larger molecular weight hyaluronic acid should be avoided and thus teaches away from the claimed invention. Applicant concluded by stating that Falk fails to establish a necessary element required for prima facie case of obviousness.

13. Applicant's arguments filed 04/19/04 have been fully considered but they are not persuasive.

To begin with, the rejection is over Falk and not Turley. However, it is respectfully noted that Turley in column 10, lines 13 and 14 discloses that "recently, it has been found that large molecular weight hyaluronic acid having a molecular weight exceeding about 1,000,000 Daltons self-aggregates and thus, does not interact very well with HA receptors. Thus, the larger molecular weight hyaluronic acid should be avoided." It is however noted that equal to about 750,000 Daltons is not in excess of 1,000,000 Daltons.

Secondly, this citation is not from Falk and less than 750,000 Daltons reads on equal to about 750,000 Daltons. Thus based on applicant's argument, the rejection is maintained and remains proper.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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